IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: TRICOR INDIRECT PURCHASER ANTITRUST LITIGATION	)	C.A. No. 05-360 (KAJ) (Consolidated)
	)	Hon. Kent Jordan, U.S.D.J.
THIS DOCUMENT RELATES TO: PACIFICARE HEALTH SYSTEMS, INC. C.A. No. 05-591 (KAJ)	)	**PUBLIC VERSION**

PLAINTIFF PACIFICARE'S RESPONSE TO
DEFENDANTS' CONSOLIDATED MOTION TO DISMISS

PUBLIC VERSION

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Defendants premise their Motion to Dismiss on mischaracterizations of PacifiCare's complaint and distortions of governing law. The anticompetitive actions of Abbott and Fournier in attempting to extend their monopoly beyond the expiration of the patent term fall within the heartland of activity prohibited by the Sherman Act. *United States v. Singer Mfg. Co.*, 374 U.S. 174, 196-97 (1963) ("[T]he possession of a valid patent . . . does not give the patentee any exemption from the provisions of the Sherman Act beyond the limits of the patent monopoly.") PacifiCare has been injured due to the defendants' unlawful tactics in protecting TriCor® ("TriCor") from generic competition. As even the defendants' own cases hold, the repeated product switches, the conduct associated with the product switches, and the pursuit of sham litigation are antitrust violations both individually and in combination with each other. Defendants' arguments depend on assuming facts at odds with those alleged in the complaint. The alleged facts, if proven, state valid claims under the antitrust laws that make any summary adjudication inappropriate, let alone a 12(b)(6) Motion to Dismiss.

I. COUNTER-STATEMENT OF THE FACTS

Defendants' Statement of Facts overlooks important allegations in the complaint and mischaracterizes others. Because the patent on the fenofibrate compound itself had expired by the time of the defendants' entry into the United States market in 1998, Abbott and Fournier protected their monopoly by other illegal means. They prevented generic drug companies from competing with TriCor through a variety of tactics. They undermined the regulatory procedures adopted by Congress designed to allow competition between brand-name and generic drugs. They filed baseless patent lawsuits

that depended on claim constructions completely at odds with the claims as defined in defendants' own patents. And they manipulated the market to ensure that no generic counterpart could effectively compete against TriCor.

A. The Regulatory Framework

Generic drugs are drugs that the Food and Drug Administration ("FDA") has found to be bioequivalent to brand-name drugs and which provide the same therapeutic effects as the brand-name drugs. PacifiCare Health Systems, Inc. First Amended Complaint ("Complaint") ¶ 19. The FDA assigns the generic drug an "AB" rating when a generic drug is bioequivalent to the brand name. *Ibid.* When a physician writes a prescription for a brand-name drug such as TriCor, that prescription allows a patient to receive the named drug or its AB-rated generic equivalent. *Id.* ¶ 21. Under state generic drug substitution laws, pharmacists may substitute a generic drug for the brand name unless the doctor has indicated specifically on the prescription that pharmacists must dispense the brand-name product. *Ibid.* A pharmacist is permitted to substitute only those generic drugs that carry the FDA's AB rating. *Ibid.*

The introduction of a generic drug into the market invariably lowers prices, as the brand-name drug now has to compete with its generic equivalent. *Id.* ¶ 22. Defendants disparage the generic drug companies' attempts to compete with TriCor, stating that these companies simply were trying to "[c]apitaliz[e] on TriCor's acceptance." Motion at 3. Yet as alleged in the complaint, Congress enacted the Hatch-Waxman Act specifically to establish an abbreviated process to expedite and facilitate the development, approval, and marketing of generic drugs. Complaint ¶ 23. To effectuate these goals, the Hatch-Waxman Act allows a generic drug manufacturer to file an "abbreviated" new drug

application ("ANDA"). An ANDA incorporates by reference the safety and effectiveness data developed and previously submitted to the FDA by the company that manufactured the original brand-name drug. *Id.*

Most relevant to this lawsuit, the Act permits a generic drug company to gain FDA approval through a "Paragraph IV Certification." In a Paragraph IV Certification, a generic drug company must certify "that the patent for the pioneer drug is invalid or will not be infringed upon by the proposed generic company's product." 21 U.S.C. § 355(j)(2)(A)(vii); *see also* Complaint ¶ 24. The generic drug manufacturer also must notify the patent owner of the filing and explain why the patent is invalid or will not be infringed. Complaint ¶ 24. The patent owner then has 45 days in which to initiate a patent infringement lawsuit against the generic drug company. If the patent owner does not initiate a lawsuit, the FDA will approve the generic product. If, however, the patent owner brings a lawsuit, Hatch-Waxman imposes an automatic stay on approval of the ANDA until the earliest of 30 months from the day the patent holder received notice of the Paragraph IV Certification, a final judicial determination of non-infringement, or the expiration of the patent. *Id.* ¶ 25.

A patentee is entitled to the 30-month stay so long as the patent is listed in the Orange Book. The Orange Book is a compilation of patents submitted to the FDA noting the patents that exist on pharmaceutical drugs. *See generally* Complaint ¶¶ 157-158. A company can list a patent in the Orange Book only where "a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1); *see also* Complaint ¶

157. A patent that is unenforceable does not meet the criteria for listing in the Orange Book. Complaint ¶ 157.

B. The First Sue and Switch

As extensively detailed in the complaint, defendants Abbott and Fournier illegally extended their monopoly in the fenofibrate market by taking advantage of the automatic 30-month stay. The defendants' first TriCor products were TriCor capsules in 67mg, 134mg, and 200mg dosages. Complaint ¶ 34. When the generic drug companies Novopharm (now Teva) and Impax filed ANDAs seeking FDA approval for these products, the defendants sued them. *Id.* ¶¶ 35-37. The first of these patent infringement lawsuits was filed on April 7, 2000. *Id.* ¶ 37. The defendants maintained that Novopharm and Impax infringed U.S. Patent No. 4,895,726 ("the '726 patent"). *Id.* ¶ 37. The lawsuit, of course, triggered the automatic 30-month stay period of the Hatch-Waxman Act. *Id.* ¶ 38.

On March 19, 2002, the United States District Court for the Northern District of Illinois granted Teva's Motion for Summary Judgment of non-infringement of the '726 patent. The decision turned on the meaning of the term "co-micronization." The court, applying black-letter law from the Federal Circuit, rejected Abbott and Fournier's interpretation of the term because their proposed interpretation was inconsistent with the claim as defined in the patent itself and with the arguments that they made to the Patent and Trademark Office. *See Abbott Labs. v. Novopharm*, 2002 U.S. Dist. LEXIS 4659 at *19-*21. (N.D. Ill. March 20, 2002) (attached as Exhibit 1 to Defendants' Motion to Dismiss) (citing *O.I. Corp. v. Tekmar Co.*, 115 F.3d 1576 (Fed. Cir. 1997)). Based on the

claim construction, the court held that Teva and Impax did not infringe the '726 patent. Complaint ¶ 39.

The Federal Circuit affirmed one year later, on March 20, 2003. *Abbott Labs. v. Novopharm*, 323 F.3d 1324 (Fed. Cir. 2003). The Federal Circuit rejected the interpretation of "co-micronization" offered by Abbott and Fournier under the doctrine that the patentee can "'cho[ose] to be his or her own lexicographer by clearly setting forth an explicit definition for a claim term.'" *Id.* (quoting *Johnson Worldwide Assocs., Inc. v. Zebco Corp.*, 175 F.3d 985, 990 (Fed. Cir. 1999)). The court held that the '726 patent itself "makes it abundantly clear that 'co-micronization' . . . should be construed" consistent with the terms of the patent and with the interpretation offered by the generic drug companies. *Ibid.*

Meanwhile, during the time that Abbott and Fournier were litigating the terms of the '726 patent, they were using the automatic 30-month stay granted by the Hatch-Waxman Act to switch the market from TriCor capsules to TriCor tablets. Complaint ¶¶ 43-45. The TriCor tablets contained slightly different dosages from the TriCor capsules – 54mg and 160mg. *Id.* ¶ 46. While the stay was in place, the defendants eliminated demand for the capsules and thus ensured that the generic manufacturers would remain unable to compete in the fenofibrate market once the court held the generic capsules to be non-infringing. *Id.* ¶¶ 44-45. As alleged in the complaint – and directly contrary to the defendants' assertions in their Motion to Dismiss – defendants' new TriCor tablets offered no marketable improvements or benefits to consumers over the TriCor capsules already on the market. *Id.* ¶¶ 47-48.

Even though the tablets did not offer any additional health benefits, the regulatory structure of Hatch-Waxman allowed the defendants' introduction of the tablets to prolong their monopoly in the fenofibrate market. *Id.* ¶ 48. Because the TriCor tablets technically were "new," no pending ANDA existed for the tablets. *Ibid.* And because the generic capsules were not the same dosage size or form as the new TriCor tablet, the generic capsule would not be AB-rated. Thus, pharmacists could not automatically substitute a generic for TriCor. And if the generic drug companies chose to file a new ANDA for a generic tablet, defendants could secure another 30 months of market exclusivity by filing another round of lawsuits. *Ibid.*

The defendants consequently set out to convert the TriCor market from capsules to tablets before Teva or Impax could introduce their generic capsule. During the 30-month stay, the defendants engaged in a variety of anticompetitive activity designed to squash any market for capsules. Specifically, they stopped selling TriCor capsules; they removed the capsules from the market; they instructed the sales force to stop detailing (marketing a drug directly to physicians) and marketing capsules; and at a substantial cost, they even destroyed part of the then-existing inventory of TriCor capsules rather than selling them. *Id.* ¶ 49.

Moreover, the defendants removed or reclassified as "obsolete" the TriCor capsule code from the National Drug Data File, also known as the NDDF. The NDDF is a widely-accepted database of available drugs that includes drug descriptions, pricing information, and indications. In excising the capsule code from the NDDF, the defendants ensured that the branded drug code reference no longer existed for purposes of generic substitution laws. Together with the defendants' removal of capsules from the

market, this de-listing made it impossible for any brand-name reference to exist for the generic capsule product when it came to market. *Id.* ¶ 51. Defendants removed the capsule code from the NDDF specifically to foreclose generic competition in the fenofibrate market. *Ibid.*

The expense of developing TriCor tablets, switching the manufacturing process to tablets, training a sales force to market the new tablets, convincing doctors to prescribe the new tablets, and eliminating the demand for TriCor capsules was extraordinary. *Id.* ¶ 52. And the cost was even more unjustified given that the end result produced a drug with no significant improvements over the drug already on the market. *Ibid.* Defendants' conduct inhibited the generic manufacturers from competing in the fenofibrate market as envisioned under the Hatch-Waxman Act and destroyed generic competition. *Id.* ¶ 54.

C. The Second Sue and Switch

The defendants' scheme did not stop with the conversion from capsules to tablets. When the market switched to tablets, the generic drug companies once again filed ANDAs in order to offer an AB-rated equivalent to the new TriCor tablet. Again, however, Abbott and Fournier sued the generic drug companies – thus triggering an automatic 30-month stay in the FDA's ability to approve the ANDA. And again, while the stay was in effect, the defendants converted the market – this time from TriCor tablets to TriCor NFE.

When Teva and Impax submitted their new ANDAs, Abbott and Fournier filed multiple patent infringement suits. Defendants knew that these patent suits were meritless because the patents they had alleged to be infringed were unenforceable and fraudulently procured. *Id.* ¶ 62-64; 79-156. Moreover, Abbott and Fournier were entitled

to the 30-month stay only because they unlawfully listed their unenforceable patents in the Orange Book. *Id.* ¶ 157-159. The defendants also knew that the lawsuit was baseless for the reasons already identified by the District Court for the Northern District of Illinois –because the defendants acted as their own lexicographer, as recognized by this Court, at least some of their proposed claim constructions had no merit. *Id.* ¶¶ 59-64. This Court granted summary judgment for the generic drug companies on three of the patents-in-suit. Abbott and Fournier then voluntarily dismissed the remnants of the lawsuits.

By the time the patent dispute was resolved, however, the defendants once again had switched the product and destroyed the generic market before the generic companies could effectively compete against the defendants' product. *Id.* ¶ 71. This time, the defendants switched to a tablet of a different dose and with a "no food effect." During the 30-month automatic stay, Abbott employed the same tactics as it had in the previous switch – it abruptly stopped selling 54mg and 160mg TriCor tablets, removed them from the market, and instructed its sales force to stop marketing them. *Ibid.* And again, the defendants removed the tablet reference code from the NDDF. *Id.* ¶ 73. In fact, the defendants removed the code on May 6, 2005 – the very same day that this Court granted the generics' motion for summary judgment. *Ibid.*

The effect of this scheme was to ensure that no brand-name reference existed for the generic product, thus preventing a generic fenofibrate tablet from being substituted for the brand-name drug. *Id.* ¶¶ 74-75. The expense of developing the different tablet, switching the manufacturing process, training a sales force, convincing doctors to prescribe the new tablet, and eliminating the demand for the old tablet was extraordinary in comparison to any purported benefit from the new tablet. *Id.* ¶ 76. And the end result

was a new version of the tablet with no significant improvements over the drug already on the market. *Id.* ¶ 77.

II. APPLICABLE LEGAL STANDARDS

When considering a Motion to Dismiss, this Court must "treat all of the allegations in the complaint as true." *Anderson v. Ayling*, 396 F.3d 265, 267 (3d Cir. 2005). To satisfy the pleading requirement, a plaintiff need only allege "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). As the Seventh Circuit recently held, "Plaintiffs need not plead facts; they need not plead law. They plead claims for relief. Usually they need do more than narrate a grievance simply and directly, so that the defendant knows what he has been accused of." *Doe v. Smith,* No. 05-1903, 2005 U.S. App. LEXIS 25051, at *2-3 (7th Cir. Nov. 21, 2005). "We have consistently rejected the argument – put forward by successive generations of lawyers representing clients defending against civil antitrust claims – that antitrust complaints merit a more rigorous pleading standard." *Twombly v. Bell Atlantic Corp.*, 425 F.3d 99, 108 (2d Cir. 2005). Moreover, "antitrust cases are less suitable candidates for dismissal at the pleading stage than some other kinds of litigation because evidence of the claimed illegality is likely to be in the exclusive control of the defendants." *Id.* at 109 (citing *Hosp. Bldg. Co. v. Trustees of Rex Hosp.*, 425 U.S. 738, 746 (1976)).

"A violation of Section 2 of the Sherman Act consists of two elements: (1) possession of monopoly power and (2) 'maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historical accident.'" *United States v. Dentsply Int'l*, 399 F.3d 181, 186 (3d Cir. 2005)

(quoting *Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451, 480 (1992)). A "company which possesses monopoly power in the relevant market will be found in violation of § 2 of the Sherman Act if the defendant willfully acquired or maintained that power." *Lepage's Inc. v. 3M*, 324 F.3d 141, 146 (3d Cir. 2003). A "monopolist willfully acquires or maintains monopoly power when it competes on some basis other than the merits." *Id.* at 147.

Moreover, the exclusionary conduct must have an anticompetitive effect. The test for establishing an anticompetitive effect "is not total foreclosure, but whether the challenged practices bar a substantial number of rivals or severely restrict the market's ambit." *Dentsply*, 399 F.3d at 191. In short, "'"[a]nticompetitive conduct" can come in too many different forms, and it is too dependent on context, for any court or commentator ever to have enumerated all the varieties.'" *Lepage's*, 324 F.3d at 152 (quoting *Caribbean Broad. Sys. v. Wireless PLC*, 148 F.3d 1080, 1087 (D.C. Cir. 1998)). It is also no excuse that an individual action might otherwise be legal. "Behavior that otherwise might comply with antitrust law may be impermissibly exclusionary when practiced by a monopolist. . . . '[A] monopolist is not free to take certain actions that a company in a competitive (or even oligopolistic) market may take.'" *Dentsply*, 399 F.3d at 187 (quoting *Lepage's*, 324 F.3d at 151-52). A monopolist retains the defense of a valid business justification for its conduct, but such a defense normally is an issue of fact for a jury. *Eastman Kodak*, 504 U.S. at 483; *see also Lepage's*, 324 F.3d at 150-51.

III. THE COMPLAINT PROPERLY ALLEGES A VIOLATION OF THE SHERMAN ACT

The defendants' conduct as alleged in the complaint violates the Sherman Act for five separate reasons. *First*, even according to the defendants' own theory, their Motion

to Dismiss should be denied because PacifiCare has alleged that the product changes were not improvements. *Second*, contrary to defendants' assertions, the product switches by themselves are actionable as anticompetitive behavior. *Third*, the conduct associated with the switches violate the Sherman Act. *Fourth*, under both Supreme Court and Third Circuit law, the combined effect of the defendants' actions in disabling generic companies from competing in the fenofibrate market establishes an antitrust violation. *Fifth*, Abbott and Fournier's litigation in the patent infringement suits against the generic companies states a valid claim under the antitrust laws.

A. The New TriCor Products Were Not Improvements Over the Old Versions of TriCor

The entire premise of the defendants' argument is that PacifiCare's complaint does not state an antitrust violation because PacifiCare has conceded that the new TriCor products were improvements over the old versions. Such an assertion however, is directly contrary to the allegations in the complaint. *See* Complaint ¶¶ 47-48, 52, 76. Thus, regardless of any other point, the Motion to Dismiss fails at the very outset because it assumes facts contrary to those alleged in the complaint.

B. The Defendants' Product Switches Are Actionable By Themselves

The defendants argue that any product switch cannot be anticompetitive, as a matter of law, so long as the new product innovation has even the most marginal of improvements over the old product. Motion to Dismiss at 9-14. While the defendants' position finds some support in older cases such as *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263 (2d Cir. 1979), and by some commentators, more recent cases such as *United States v. Microsoft*, 253 F.3d 34, 64-67 (D.C. Cir. 2001), and *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1382 (Fed. Cir. 1998), hold that courts either should

conduct a balancing test between the proffered benefit of the new product and the anticompetitive effect, or examine the monopolist's reasons for the product switch. An examination of the motive and effect of the switch is especially appropriate in the generic/brand-name drug context, where the entire purpose of the regulatory structure is to allow generic drug manufacturers to copy the brand-name drug that has been on the market for years. *Cf. Lepage's*, 324 F.3d at 152 (whether a violation of Section 2 has occurred is "dependent on context") (internal quotation marks omitted).

1. The *Microsoft* Balancing Test

In *United States v. Microsoft*, the defendant Microsoft made the very same arguments that Abbott and Fournier now make to this Court – that a product innovation is per se lawful. 253 F.3d at 65. The *Microsoft* court, however, rejected such an argument and cited many of the same cases upon which Abbott and Fournier rely in this Court: "Judicial deference to product innovation . . . does not mean that a monopolist's product design decisions are per se lawful." *Ibid.* (citing *Foremost Pro Color, Inc. v. Eastman Kodak Co.*, 703 F.2d 534, 546 (9th Cir. 1983); *California Computer Prods., Inc. v. IBM*, 613 F.2d 727, 739, 744 (9th Cir. 1979); *In re IBM Peripheral EDP Devices Antitrust Litig.*, 481 F. Supp. 965, 1007-08 (N.D. Cal. 1979)). The *Microsoft* court held that three of Microsoft's product innovations in making changes to its Internet Explorer were anticompetitive because these innovations had "the effect of significantly reducing usage of rivals' products and hence protecting its own operating system monopoly." *Id.* at 65; *see also id.* at 66. The court then engaged in a balancing test to determine whether "the anticompetitive effect of the challenged action outweighs" the defendant's proffered justification. *Id.* at 67. The court ruled that two of Microsoft's three innovations were

unlawful. *Ibid.* *See also id.* at 75 ("In order to violate the antitrust laws, the incompatible product must have an anticompetitive effect that outweighs any procompetitive justification for the design.").

PacifiCare has alleged specifically that in the first product switch, Abbott and Fournier's new drug application for TriCor "offered no marketable improvements or benefits to consumers." Complaint ¶ 47. This new tablet had "no significant improvements over the drug already on the market." *Id.* ¶ 52. Likewise, in the second product switch, the new product had "no significant improvements over the drug already on the market," and the defendants' purpose was to maintain their monopoly *Id.* ¶¶ 76-77. These allegations are sufficient to survive a Motion to Dismiss, as the question whether the anticompetitive effect outweighs any potential product improvement is a paradigmatic question of fact.

2. The "Purpose" Test

Other cases apply a slightly different standard in evaluating the antitrust implications of a product change, finding a violation where the monopolist's purpose in introducing the new product is an anticompetitive one. For example, in *C.R. Bard v. M3 Systems*, 157 F.3d at 1382, the Federal Circuit affirmed a jury verdict that found an antitrust violation where a defendant modified its product in a manner that inhibited competition. *C.R. Bard* involved a company that made a medical gun where the firing device was a needle. The defendant modified its gun to prevent competitors from selling "copycat" needles for the guns. *Ibid.* The Federal Circuit held that where a company makes a product change "for the purpose of injuring competitors in the replacement needle market, rather than for improving the operation of a gun," an antitrust violation

exists. *Ibid.* While the defendant maintained at trial that it modified its gun to make it easier to load and unload, the Federal Circuit affirmed that the "real reasons for modifying its gun were to raise the cost of entry to potential makers of replacement needles, to make doctors apprehensive about using non-Bard needles, and to preclude the use of 'copycat' needles." *Ibid.* Thus, under *C.R. Bard*, so long as a plaintiff alleges that the "real reason" for the product change was an anticompetitive one, a valid antitrust claim exists. *Cf.* Complaint ¶¶ 53, 77.

Abbott and Fournier discuss *C.R. Bard* only briefly. In attempting to distinguish *C.R. Bard*, the defendants maintain that the case is inapplicable because "the court never actually reached the question of plaintiff's new foreclosure theory." Motion to Dismiss at 10 n.7. Yet the defendants misread *C.R. Bard* on two different levels. *First*, the court in *C.R. Bard* did reach the question that the defendants claim the court avoided – whether a plaintiff can prove an antitrust violation by showing that the defendant changed its product for anticompetitive reasons. Abbott and Fournier base their argument on the paragraph following the "product change" discussion, where the court declined to consider a separate assertion raised by the defendant because the defendant did not object to the jury instructions. *See C.R. Bard*, 157 F.3d at 1382 ("The dissent also takes issue with the jury instructions . . . .) (emphasis added). As Judge Newman's dissent shows, her objection to the jury instructions was her concern that in determining whether the patentee had engaged in exclusionary conduct, "[n]o mention was made of the patentee's statutory right to exclude, and there was no instruction to consider that right." *Id.* at 1370 (Newman, J., dissenting).

Second, the Federal Circuit was not applying a "new" rule when it held that a plaintiff can show an antitrust violation by proving that the defendant made a product change "for the purpose of injuring competitors." *Id.* at 1382. Indeed, the *C.R. Bard* court cited *In re IBM Peripheral EDP Devices*, 481 F. Supp. at 1002 – a case not only cited in *Microsoft*, but also cited by Abbott and Fournier in this case. Motion to Dismiss at 9-10.[1]

Likewise, in *Multistate Legal Studies, Inc. v. Harcourt Brace Jovanovich Legal and Prof'l Pubs., Inc.*, 63 F.3d 1540, 1551 (10th Cir. 1995), the court held that "[b]oth the purpose and results of a product change, including customers' reception of the change, are relevant to whether a claimed product improvement is pro- or anticompetitive." The Tenth Circuit specifically rejected the Areeda/Hovenkamp analysis that a product change should be presumptively legal. It noted: "Where, as here, however, the claimed product improvement takes the form of a marketing change, rather than some complex technological integration of previously separate functions, our degree of deference to product designers is reduced." *Id.* at 1551 n.10. The court evaluated the purpose of the product change along with its effect, and held that the plaintiff had created issues of triable fact sufficient to survive summary judgment. *Id.* at 1551.

The principle that a company cannot change its product for anticompetitive purposes also is consistent with *Berkey Photo*. Although the court in *Berkey Photo* stated that the plaintiff could not "complain of a product introduction" because "any firm, even a monopolist, may generally bring its products to market whenever or however it

[1] In *Medtronic Minimed, Inc v. Smiths Medical MD, Inc.*, 371 F. Supp. 2d 578 (D. Del. 2005), this Court did not discuss *C.R. Bard*'s anticompetitive purpose rationale. Indeed, the facts as discussed in the opinion showed that the defendant did not have an anticompetitive purpose. Moreover, contrary to the defendant in *Medtronic* – and like the defendant in *C.R. Bard*, the defendants here affirmatively misused their patent.

chooses," 603 F.2d at 286 (emphasis added), the court also recognized an exception to this rule. The court stated that "the situation might be completely different if, upon the introduction of the 110 system, Kodak had ceased producing film in the 126 size." *Id.* at 287 n.39. This "completely different" situation is exactly what happened in this case – Abbott and Fournier "ceased producing" the old versions of TriCor for the purpose of maintaining their monopoly in the fenofibrate market.

Abbott and Fournier understand that the only way they can prevail is with a per se rule that any improvement, no matter how slight or meaningless, results in antitrust immunity. PacifiCare has pleaded -- and the evidence will show -- that Abbott and Fournier's purpose for the product switch was to maintain their monopoly. Complaint ¶¶ 53, 76-77. And the effect of the product switch was to foreclose competition. *Id.* ¶¶ 53-55, 77-78.

3. This Case Is Different From All Other Product Switch Cases

The other cases involving product changes were of a completely different type than the case at bar. In those cases, the change was in a product that interfaced with the allegedly monopolized market. The companies did not change the product that was in the market itself. *Cf. C.R. Bard*, 157 F.3d at 1371-72 (Newman, J., dissenting) ("'Where competitors' products must interface with the monopolist's product the monopolist's introduction of a new product that makes that interconnection more difficult or expensive might violate Section 2, although no court has specifically so held.'") (quoting the pre-*Microsoft* 1 American Bar Assoc., *Antitrust Law Developments* 286 (4th ed. 1997)). Thus, in *Berkey Photo*, 603 F.2d at 267-68, and *Foremost Pro Color, Inc. v. Eastman Kodak*, 703 F.2d 534, 537 (9th Cir. 1983), the complaint involved the introduction of a

new camera that affected the market for photofinishing services. In *In re IBM Peripheral EDP Devices*, 481 F. Supp. at 1005, and *California Computer Prods., Inc. v. IBM*, 613 F.2d 727, 739 (9th Cir. 1979), the issue concerned changes in the computer's central processing unit that affected the market for plug-compatible devices. Likewise, in those cases finding in favor of liability, the issue revolved around changes to one product that caused an effect in another market, such as changes in Windows that made it more difficult for the Netscape Internet browser to compete against Microsoft's Internet Explorer, or changes to the medical gun that made it impossible for a consumer to use competing needles.

Here, by contrast, the product change is in the very market where the generic companies compete against Abbott and Fournier. As the defendants do not contest, the relevant market in this case is fenofibrate itself. Complaint ¶ 17. The defendants' constantly-shifting monopoly product effectively prevents any generic drug company from competing in the fenofibrate market. With the product switch, Abbott and Fournier destroyed the market for the old TriCor. As established by Hatch-Waxman, the success of generic drugs depends upon whether a brand-name counterpart exists. Knowing this fact, Abbott and Fournier used the 30-month stay of Hatch-Waxman to introduce a slightly different version of TriCor that prevented the generic drug from receiving an AB rating.

Switching the product in a monopolized market is different in kind from improving a product in a related market. Whereas a court might be wary of weighing the complex tradeoffs between changes to one product and its effect in a different market, no such issues are present in a case such as this. Because the product switch here does not

involve any integration issues, a per se rule of legality is especially inappropriate. *Multistate Legal Studies*, 63 F.3d at 1551 n.10. Indeed, even Professors Areeda and Hovenkamp concede that a per se rule of legality for product improvements is not appropriate where "the defendant's position in the dominant product is so substantial that the market for the older technology is eliminated." Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law--An Analysis of Antitrust Principles and Their Application* ¶ 776a (1997).

In a case where the monopolist switches the product in the monopolized market itself, the question of anticompetitive effect versus any procompetitive justification becomes much more straightforward and easier to balance. Here, a monopolist is leaping from product to product in the very market in which it is suppressing competition, for the stated purpose of squelching any ability of competing products to emerge. *Cf. Microsoft*, 253 F.3d at 75 (upholding one of Microsoft's product innovations because it "does not itself have any anticompetitive effect") (emphasis added). Antitrust law permits a court or jury to determine whether any procompetitive aspects of the switch justify this blatantly anticompetitive practice. As the Second Circuit explained post-*Berkey Photo*, the "introduction of a new product may violate § 2 if a monopolist acts to compel customer choice by withdrawing a substitute product from the market." *Northeastern Tel. Co. v. American Tel. and Tel. Co.*, 651 F.2d 76, 93 n.10 (2d Cir. 1979).

Abbott and Fournier did not give consumers, physicians, or pharmacists the ability to choose between TriCor and an AB-rated generic. In these circumstances, the product switch alone violates the Sherman Act. The defendants' purpose was to stifle the emergence of generic drugs and undermine the regulatory regime that promotes

competition between generic and brand-name drugs. *Cf. Sargent-Welch Scientific Co. v. Ventron Corp.*, 567 F.2d 701, 711 (7th Cir. 1977) ("[T]he possessor of lawfully acquired monopoly power may not use that power as leverage to deprive competitors of access to customers, to force customers to maintain resale prices, or in any other coercive manner."). The effect of the defendants' actions was to suppress competition from generic drugs in the fenofibrate market, depriving consumers and end-payers of the benefits of a competitive market. Thus, under any sort of balancing test or purpose-driven analysis, PacifiCare has adequately pleaded an antitrust violation due to the product switch alone.

C. The Activity Associated With the Product Switch Violates the Sherman Act

Regardless of whether the switch itself is actionable, Abbott and Fournier's own cases establish that their anticompetitive actions in carrying out the switch are actionable. Indeed, in *Berkey Photo* the court specifically rejected Kodak's argument "that new product introductions are Ipso facto immune from antitrust scrutiny." 603 F.2d at 286 n.30. The court noted that the "associated conduct" with the product introduction "supplies the violation." *Ibid.*

Here, even if the product switch itself is lawful, Abbott and Fournier's anti-competitive actions in implementing the switch are illegal. Abbott and Fournier did not simply change the product and let the market decide for itself whether it preferred a generic version of the old TriCor to the new brand-name TriCor. Instead, Abbott and Fournier undertook a systematic campaign to ensure that no AB-rated generic could ever compete against TriCor. Abbott and Fournier wanted to evade Hatch-Waxman's mandate to lower prices through the introduction of generic drugs into the marketplace.

Hatch-Waxman, after all, was entitled the 1984 Drug Price Competition and Patent Term Restoration Act when Congress originally enacted it. *See* P.L. 98-417, 98 Stat. 1538 (Sep. 24, 1984) (emphasis added).

Instead, however, Abbott and Fournier devised a formula to inhibit competition: File a patent infringement lawsuit 45 days after receiving notice of a generic drug company's intention to make a generic version of TriCor. Complaint ¶ 37. List an unenforceable patent in the Orange Book to ensure a 30-month stay. *Id.* ¶ 157-179, 181. Develop a new TriCor product that is substantially similar to the old product but does not allow the generic version of the old product to obtain an AB rating. *Id.* ¶¶ 47, 48, 70, 75, 76. Use the automatic 30-month stay to phase out the old TriCor and introduce the new version before the generic drug of the old version could receive final approval by the FDA. *Id.* ¶¶ 38, 43-44. During the 30-month stay, stop selling the old version of TriCor. *Id.* ¶ 49. Instruct the sales force to stop detailing and marketing the old TriCor. *Ibid.* Buy back the old version from pharmacies and destroy the inventory at a substantial cost. *Ibid.* Switch the manufacturing process to the new version. *Id.* ¶ 52. Market only the new version. *Id.* ¶ 50. Ensure that no brand-name reference can exist for a generic version of the old product by de-listing the old product from the National Drug Data File. *Id.* ¶ 51. Develop an even-newer version of TriCor to be ready to change the product again once the generic drug company files another ANDA. *Id.* ¶¶ 56-59. Rinse and repeat.

All these actions, both independently and taken together, violate the Sherman Act. Abbott and Fournier do not appear to deny – and indeed cannot deny on a Rule 12(b)(6) motion – that these activities in implementing the product switch were anticompetitive

and done with the purpose of preventing competition in the fenofibrate market. *Cf.* Complaint ¶¶ 53-54, 77-78. Instead, defendants argue that they have no duty to maintain discontinued products in the marketplace and can de-list products from the NDDF whenever they choose. Motion to Dismiss at 14-17. Defendants' arguments, however, miss the point for five reasons, any one of which is sufficient for this Court to deny their Motion to Dismiss.

First, and most fundamentally, the defendants' apparent concession that the activities implementing the switch are anticompetitive fatally dooms this Motion to Dismiss. Defendants are monopolists, and therefore cannot take actions designed to maintain their monopoly that are in violation of the antitrust laws. *See Dentsply*, 399 F.3d at 187; *Lepage's*, 324 F.3d at 151-52. Regardless of the switch itself, PacifiCare has alleged that Abbott and Fournier performed the other actions with anticompetitive intent and with an anticompetitive effect. For example, even if de-listing a drug from the NDDF is not illegal per se, it is illegal where, as here, a monopolist does it with the purpose of stifling the ability of generic drugs to compete against the monopolist's brand-name product.

Second, the defendants' citation of cases that a monopolist is under no duty to aid competitors is unavailing because these cases are not on point. Motion to Dismiss at 14. While Abbott and Fournier are not under a duty to aid their competitors, the entire purpose of the antitrust laws is to prevent a monopolist from taking affirmative steps to harm competition. PacifiCare asks only for a competitive market as envisioned by the regulatory structure itself – a market where pharmacists and physicians are able to substitute a generic drug for its brand-name equivalent. Abbott and Fournier did not

allow the market to operate freely. By, among other things, marketing only the reconstituted version of the same drug, buying back the old version, and de-listing the old code reference, Abbott and Fournier changed the market dynamics to maintain their monopoly.

These actions, independent of the introduction of the new product itself, were anticompetitive because they "severely restrict[ed] the market's ambit." *Dentsply*, 399 F.3d at 191. They short-circuited the goals of Hatch-Waxman by preventing consumers from substituting generic fenofibrate for the brand-name drug. Complaint ¶ 74. The generic drug companies do not need the help of Abbott or Fournier to ensure a competitive market. They did not ask to "conscript" Abbott's "salesmen" or ask them to "[a]dvertise . . . free of charge." *Olympia Equip. Leasing Co. v. Western Union Tel. Co.*, 797 F.2d 370, 377-78 (7th Cir. 1986). PacifiCare only needs Abbott and Fournier to stop interfering with the lawful functioning of the market. The harm to competition occurred because Abbott and Fournier manipulated the regulatory regime and made it impossible to substitute generics for the brand-name drug.

Third, the First Amendment does not immunize the defendants' actions in de-listing TriCor from the NDDF. This de-listing is an independent antitrust violation. Recognizing the anticompetitive purpose and effect of de-listing the drug, Abbott and Fournier have cited only one case in an attempt to escape the consequences of their actions -- *Ibanez v. Florida Dep't of Bus. and Prof. Reg. Bd. of Accountancy*, 512 U.S. 136 (1994). But *Ibanez* does not concern antitrust immunity at all. While the Supreme Court has recognized the *Noerr-Pennington* exception to antitrust liability in order to safeguard the First Amendment, it has not extended *Noerr-Pennington* to other contexts.

Abbott and Fournier now ask this Court to create a new form of antitrust immunity that would permit a monopolist to say or do any anticompetitive activity so long as it was truthful. The defendants have not cited any caselaw in support of this radical proposition, nor can they.

Indeed, "[i]t is well settled that First Amendment rights are not immunized from regulation when they are used an integral part of conduct which violates a valid statute." *California Motor Transport Co. v. Trucking Unlimited*, 404 U.S. 508, 514 (1972). "First Amendment rights may not be used as the means or the pretext for achieving 'substantive evils' . . . . Certainly the constitutionality of the antitrust laws is not open to debate. . . . If the end result is unlawful, it matters not that the means used in violation may be lawful." *Id.* at 515. *See also F.T.C. v. Superior Court Trial Lawyers Ass'n*, 493 U.S. 411, 428 n.12 (1990) ("The right of business entities to 'associate' to suppress competition may be curtailed") (internal quotations omitted); *Associated Press v. United States*, 326 U.S. 1 (1945) (press not immune from First Amendment scrutiny). *Cf. Microsoft*, 253 F.3d at 63 (rejecting defendant's claim that its right to use intellectual property conferred antitrust immunity, stating that the defendant's argument "is no more correct than the use of one's personal property, such as a baseball bat, cannot give rise to tort liability").

Fourth, the mere fact that the defendants' NDDF de-listing did not completely foreclose the ability of the generic companies to sell fenofibrate products is irrelevant. As the Third Circuit explicitly recognizes, the test for establishing an anticompetitive effect "is not total foreclosure, but whether the challenged practices bar a substantial number of rivals or severely restrict the market's ambit." *Dentsply*, 399 F.3d at 191. Here, the complaint alleges and the evidence will show such a severe restriction.

Complaint ¶¶ 54-55, 78. Thus, it is of no import that despite the de-listing, the generic drug companies could continue to sell fenofibrate products. The de-listing alone was anticompetitive because it impeded the generic drug companies from selling their product as a generic substitution for the brand-name version. This action cut off the generics' main avenue for distribution and ensured that Abbott and Fournier could maintain their monopoly on the fenofibrate market. *C.f. Lepage's*, 324 F.3d at 155, 160 (finding an anticompetitive effect where a monopolist's actions "foreclose[d] portions of the market to a potential competitor" and "cut [the plaintiff] off from key retail pipelines necessary to permit it to compete profitably").

Fifth, Abbott and Fournier cannot escape the anticompetitive consequences of knowingly listing an invalid patent in the Orange Book. This activity standing alone establishes an antitrust violation. Indeed, in *In re Remeron Antitrust Litig.*, 335 F. Supp. 2d 522, 531 (D.N.J. 2004), the court held that the defendant's late listing of a patent in the Orange Book stated a claim under the Sherman Act because of its anticompetitive effect. The court noted that "[t]he Third Circuit has similarly held that improper use of a patent can be a Section 2 violation." *Ibid.* (citing *SmithKline Corp. v. Eli Lilly & Co.*, 575 F.2d 1056 (3d Cir. 1978)). *See also In re Buspirone Patent Litig.*, 185 F. Supp. 2d 363, 369-73, 376-77 (S.D.N.Y. 2002) (bad-faith listing of patent in the Orange Book is anticompetitive and not subject to *Noerr-Pennington* immunity).

Here, as alleged in the complaint, the defendants knew the patents were unenforceable and therefore were inappropriate for listing in the Orange Book. Complaint ¶¶ 157, 160, 162-170, 172-175. Moreover, the defendants listed an unenforceable patent in the Orange Book for anticompetitive purposes. Complaint ¶¶

158, 161, 171, 176. Abbott and Fournier's only response to these allegations is a non-sequiter, arguing in one sentence that this allegation is simply an attempt to plead around the *Walker Process* standard for fraud on the patent office. But the defendants completely miss the point of the anticompetitive consequences of their actions. As alleged in the complaint, listing the patents in the Orange Book was an anticompetitive action by itself and also was one part of the defendants' overall scheme to maintain their monopoly in the fenofibrate market.

All these actions – de-listing the drug from the NDDF, knowingly listing unenforceable patents in the Orange Book, ensuring that no old product remained before they introduced the new product, buying back the old product at a loss, using the 30-month stay to switch the product, instructing their sales force not to market the old drug – both independently and in combination are anticompetitive wholly apart from the product switch itself. Under Third Circuit law and indeed under *Berkey Photo*, these allegations show a violation of the Sherman Act.

D. The Combined Effect of the Defendants' Practices Is Anticompetitive

It is black-letter law that in determining whether a violation of the Sherman Act has occurred, "[t]he relevant inquiry is the anticompetitive effect of [a monopolist's] exclusionary practices considered together." *Lepage's*, 324 F.3d at 162. In *Continental Ore Co. v. Union Carbide Corp.*, 370 U.S. 690, 699 (1962), the Supreme Court stated that "the duty of the jury was to look at the whole picture and not merely at the individual figures in it" (internal quotation omitted). Thus, wholly apart from the individual acts, Abbott and Fournier have violated the Sherman Act through an overall scheme to monopolize the fenofibrate market. *See also Lepage's*, 324 F.3d at 162 (citing

Continental Ore for the proposition that "[t]he relevant inquiry is the anticompetitive effect of 3M's exclusionary practices considered together"); *Biovail Corp. v. Hoescht Aktiengesellschaft*, 49 F. Supp. 2d 750, 759-60, 772 (D.N.J. 1999) (denying defendant pharmaceutical corporation's Motion to Dismiss a complaint alleging that the defendant monopolized the market through anticompetitive tactics in keeping a generic drug off the market because of the defendant's overall scheme to monopolize); *In re Remeron*, 335 F. Supp. 2d at 528 (denying defendant pharmaceutical corporation's Motion to Dismiss despite that none of the actions was illegal individually, plaintiff had alleged an overall scheme of anticompetitive behavior that "rests upon determinations that flow from factual allegations").

Abbott and Fournier do not seriously attempt to argue that PacifiCare's allegation of an overall scheme of anticompetitive activities fails to state a claim. Their only arguments are (1) that a plaintiff must allege wrongful conduct; and (2) that the overall scheme "hinges" on acts and conduct immunized by the First Amendment under the *Noerr-Pennington* doctrine. Motion to Dismiss at 29-30. Both arguments are unavailing.

First, as demonstrated in spades above, PacifiCare has alleged wrongful conduct. The overall effect of defendants' actions was to prevent doctors and pharmacists from substituting a generic fenofibrate for the brand-name version. Even if the product switch itself was not anticompetitive, even if stopping selling the old version was not anticompetitive, even if buying back and destroying the inventory of the old version was not anticompetitive, even if listing a knowingly unenforceable patent in the Orange Book was not anticompetitive, and even if de-listing the old version from the NDDF was not anticompetitive, the combined effect of all these actions plus the others detailed in the

complaint was to foreclose substitution of a generic drug for the brand name. These actions adversely affected competition by cutting off the primary method by which generics compete in the marketplace.

Moreover, Abbott and Fournier undermined the very purpose of the Hatch-Waxman Act, which was enacted to allow competition and lower prices by making it easier for generic drugs to gain FDA approval. Instead, however, the defendants attempted to game the system and maintain their monopoly by preventing the substitution of TriCor for generic equivalents. *Cf. Lepage's*, 324 F.3d at 152 (noting that a violation of Section 2 is "too dependent upon context for any court ever to have enumerated all the varieties") (internal quotation marks omitted). Regardless of the legality of these actions standing alone, together they allowed the defendant monopolists "to foreclose competition [and] gain a competitive advantage." *Dentsply*, 399 F.3d at 186 (quoting *Eastman Kodak*, 504 U.S. at 482-83). And even if lawful when practiced by someone else, these actions as carried out by a monopolist were illegal because the combined effect was to stifle competition. *Dentsply*, 399 F.3d at 187.

Second, as evidenced directly above, the overall scheme of anticompetitive behavior does not "hinge" on any allegation of sham litigation. While the sham litigation is another example of anticompetitive activity as discussed in Part III.E, PacifiCare's allegations of anticompetitive activity in no way depend on a finding that the prior litigation was a sham. Abbott and Fournier manipulated the market to extend their monopoly on fenofibrates, regardless of whether they brought their patent infringement lawsuits in good faith.

E. The Defendants' Patent Litigation Violates the Sherman Act

Abbott and Fournier's litigation conduct violates the Sherman Act for two different reasons. *First*, regardless of whether the litigations were shams, the lawsuits violate the Sherman Act as part of the defendants' overall scheme to suppress competition. *Second*, both sets of patent litigation were shams under the standards of *Professional Real Estate Investors, Inc. v. Columbia Pictures Indus.*, 508 U.S. 49, 60 (1993) ("*PRE*").

1. The Litigation Was One Part of the Defendants' Overall Scheme of Monopolization

Regardless of whether the patent infringement lawsuits were shams, the fact of litigation itself nevertheless may be anticompetitive as part of an overall scheme of monopolization. *Singer Mfg.*, 374 U.S. at 174; *Trucking Unlimited*, 404 U.S. at 513-514; *Clipper Exxpress v. Rocky Mountain Motor Tariff Bureau*, 690 F.2d 1240, 1263-64 (9th Cir. 1982). In *Singer Manufacturing*, the Supreme Court specifically found a violation of the Sherman Act because of the defendants' enforcement of a valid patent. 374 U.S. at 194-95. The defendant violated the Sherman Act because the defendant shared a "common purpose to suppress the Japanese machine competition in the United States through the use of the patent." *Id.* at 195. And in *Trucking Unlimited*, the Supreme Court again reaffirmed that the First Amendment does not immunize activities used as part of an overall scheme to violate the Sherman Act. 404 U.S. at 513-14.

In *Clipper Exxpress*, the court specifically held that an antitrust violation involving an overall scheme to monopolize "does not enjoy immunity simply because an element of that violation involves an action which itself is not illegal." 690 F.2d at 1263. The court continued, "[W]e hold that when there is a conspiracy prohibited by the

antitrust laws, and the otherwise legal litigation is nothing but an act in furtherance of that conspiracy, general antitrust principles apply, notwithstanding the existence of *Noerr* immunity." *Ibid.* Thus, the court allowed the plaintiff to maintain its "overall scheme" allegation: "If Clipper can prove that the defendants engaged in activities which violated the antitrust laws, those violations do not become immune simply because the defendants used legal means . . . as a means to enforce the violations." *Id.* at 1264. *See also Handgards, Inc. v. Ethicon, Inc.*, 601 F.2d 986, 994 (9th Cir. 1979) ("a patentee may incur antitrust liability for even the good faith prosecution of a valid patent where it is shown that the infringement suit was brought in furtherance and as an integral part of a plan to violate the antitrust laws.") (internal quotation marks omitted); *Atari Games Corp. v. Nintendo of Am., Inc.*, 897 F.2d 1572, 1576-77 (Fed. Cir. 1990) ("patent owners may incur antitrust liability . . . where there is an overall scheme to use the patent to violate antitrust laws"). Thus, this Court can consider Abbott and Fournier's actions in the underlying patent litigation as evidence of the defendants' overall scheme to monopolize, regardless of whether the litigation was sham litigation.

2. The Patent Lawsuits Were Sham Litigation

The litigation also independently states a violation of the Sherman Act because they were sham lawsuits. Abbott and Fournier correctly state the test for whether a lawsuit qualifies as sham litigation under the *Noerr-Pennington* doctrine. *First*, the lawsuit must be "objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits." *PRE*, 508 U.S. at 60. *Second*, if the lawsuit is objectively baseless, the court examines a defendant's subjective motivation. This

second prong is satisfied where the lawsuit conceals "an attempt to interfere directly with the business relationships of a competitor." *Id.* at 61.

In their Motion, Abbott and Fournier do not contest the second prong of this test, and for good reason. PacifiCare's complaint alleges that the defendants used the lawsuits as a means to inhibit the generic drug companies from competing in the fenofibrate market. Complaint ¶¶ 43-44, 49, 53, 62-64, 69-71. Thus, the success of the defendants' argument turns on whether, as a matter of law, the defendants have shown that the patent lawsuits were not objectively baseless. Here, both the first round of patent lawsuits about the '726 patent in Illinois and the second round of patent lawsuits in this Court were objectively baseless.

a. The Capsule Litigation

All parties agree that both the District Court and the Federal Circuit summarily rejected the first round of infringement lawsuits brought by Abbott and Fournier regarding the TriCor capsule. *See Abbott Labs. v. Novopharm*, 2002 U.S. Dist. LEXIS 4659 (N.D. Ill. March 20, 2002); *Abbott Labs. v. Novopharm*, 323 F.3d 1324 (Fed. Cir. 2003). Abbott and Fournier make three arguments to justify the objective validity of these lawsuits. All are unavailing.

First, Abbott and Fournier boldly assert that Teva and Impax's failure to allege a sham litigation claim in the original lawsuits is evidence that the claims had merit. But the generic drug companies' failure to raise the claim five years ago sheds no light on the actual merits of the claim now, let alone does it serve as some sort of judicial estoppel that would prevent the non-competitor plaintiffs from raising this claim in this Court. A lawsuit is either objectively baseless or it is not. Abbott and Fournier's argument is

exactly what they assert is wrong with plaintiffs' complaints – they are injecting subjective motivation into an analysis of the objective merits of the litigation. The subjective motivation of Teva and Impax is unimportant. What matters is whether the litigation was objectively baseless.

Second, Abbott and Fournier argue that a dismissal on summary adjudication does not mean that a lawsuit is objectively meritless. This argument, however, is nothing but a straw man. That summary judgment was granted in the capsule litigation only helps PacifiCare. *See, e.g., In re Relafen Antitrust Litig.*, 346 F. Supp. 2d 349, 361-63 (D. Mass. 2004) ("a court may, in the course of resolving the underlying litigation, make findings tantamount to a finding that the litigant's conduct was objectively baseless") (internal quotations and alterations omitted). The four judges who examined the matter all disposed of Abbott and Fournier's arguments quite easily. Indeed, a unanimous panel of the Federal Circuit concluded that the patent itself "makes it abundantly clear" that the defendants' proposed claim construction was wrong. *Abbott Labs. v. Novopharm*, 323 F.3d at 1330. Moreover, PacifiCare's claim of sham litigation is not based on the mere fact that summary judgment was granted. Rather, the opinions themselves show that the claims were objectively baseless, and discovery would shed even more light on this point.

Third, Abbott and Fournier maintain that a review of the opinions in the capsule litigation shows why their arguments were reasonable. But the opinions demonstrate exactly the opposite. As discussed in more detail in Part I, *supra*, Abbott and Fournier's argument depended entirely on claim construction. Under the law at the time and today, "[t]he written description and any drawings are reviewed to determine if the patentee chose to set forth an explicit definition that is different in scope from that of the ordinary

meaning." *Abbott Labs.*, 2002 U.S. Dist. LEXIS 4659 at *13. The district court found, and the Federal Circuit affirmed, a claim construction contrary to Abbott and Fournier's proposed interpretation because "the patentee 'has chosen to be his or her own lexicographer by clearly setting forth an explicit definition for a claim term.'" *Abbott v. Novopharm*, 323 F.3d at 1330 (quoting *Johnson Worldwide Assocs., Inc. v. Zebco Corp.*, 175 F.3d 985, 990 (Fed. Cir. 1999)). Indeed, in *In re Buspirone*, 185 F. Supp. 2d at 372, the court found that a patent infringement lawsuit brought by a drug company against a generic manufacturer was objectively baseless because a "straightforward application of governing patent law" established that the claims were invalid. Given the black-letter law on patent interpretation, and the lawsuit's total dependence on a claim construction directly at odds with the term as defined in the patent, a reasonable factfinder could find that the lawsuit was objectively baseless.

b. The Tablet Litigation

Two independent reasons exist for why Abbott and Fournier's lawsuits in this Court alleging infringement also were objectively baseless. *First*, the defendants' inequitable conduct in procuring the patents meant that Abbott and Fournier were attempting to enforce a knowingly unenforceable patent. *Second*, regardless of the enforceability issue, the defendants' arguments were objectively baseless.

1. PacifiCare Has Alleged a Valid Sham Litigation Claim in the Tablet Litigation Due to Defendants' Fraud on the Patent Office

First, PacifiCare has adequately alleged that the tablet litigation was a sham because the defendants knew the patents were unenforceable. Abbott and Fournier therefore knew that the tablet litigation was objectively baseless. *PRE*, 508 U.S. at 660. Furthermore, they initiated the lawsuit for anticompetitive reasons. *Ibid.* Abbott and

Fournier argue that PacifiCare "tries to twist *PRE*'s objective standard into a purely subjective one," but defendants are once again mistaken. Motion to Dismiss at 22. The tablet litigation was objectively baseless because the patents at issue were unenforceable. Complaint ¶¶ 79-156. This allegation does not twist an objective standard into a subjective one. No reasonable litigant in the defendants' shoes would reasonably expect success on the merits in litigating a knowingly unenforceable patent. *PRE*, 508 U.S. at 60.

Under the defendants' view, no sham litigation claim would ever be appropriate where the defendants had possession of knowledge that would render the lawsuit baseless. For example, defendants would have this Court hold that a plaintiff bringing an action to enforce a contract that it knew to be fraudulent would not have instituted a sham litigation because under the fraudulent contract, a valid breach of contract claim existed. But the whole point is that the contract is invalid, thus rendering the underlying claim unenforceable. Likewise, a claim based upon an unenforceable patent is objectively baseless if the antitrust defendant brings an infringement action knowing that the patent is unenforceable. *See also In re Relafen*, 346 F. Supp. 2d at 361-63 (analyzing whether the defendants knew the patent was invalid at the time of suit under *Noerr-Pennington* and refusing to grant defendant's Motion to Dismiss because of fact issues surrounding the defendant's knowledge).

A plaintiff alleging sham litigation must of course show that the subjective intent in bringing the lawsuit was anticompetitive. *PRE*, 508 U.S. at 60. This second prong of *PRE* is independent of whether the lawsuit was baseless, and goes only to the issue of anticompetitive intent. *Ibid.* And in this Motion to Dismiss, defendants have not

contested their anticompetitive intent in instituting the tablet litigation. Here, the tablet litigation establishes an independent violation of the Sherman Act because PacifiCare has adequately alleged that the tablet litigation was objectively baseless. Abbott and Fournier knew that the lawsuits ultimately would fail due to the inequitable conduct in procuring the patents. Complaint ¶¶ 62-64, 76-156, 181. [2]

2. The Tablet Litigation Was a Sham Because Defendants' Arguments Were Objectively Baseless

The tablet litigation in this Court also was sham litigation because the defendants' arguments were objectively baseless. Abbott and Fournier rely entirely on *Twin City Bakery Workers & Welfare Fund v. Astra Aktiebolag*, 207 F. Supp. 2d 221 (S.D.N.Y. 2002). *Twin City Bakery*, however, is inapplicable here because the lawsuits in *Twin City Bakery* were not dismissed, as they were here. Abbott and Fournier argue that their voluntary dismissal of the tablet lawsuits is of no import, although they cite no law to support their position. But Abbott and Fournier's voluntary dismissal of the complaint creates a triable issue of fact as to whether the lawsuits were objectively baseless. The fact that Abbott and Fournier prevailed on parts of the summary judgment ruling does not mean that they ultimately would have prevailed on the issue. Indeed, their voluntary dismissal is a strong suggestion that they would not have prevailed, as they themselves did not think that their arguments had merit.

Abbott and Fournier attempt to escape the import of their voluntary dismissal by arguing that they dismissed the lawsuit because "the litigation was moot from a practical standpoint." Motion to Dismiss at 24. But the defendants' argument has a fatal flaw.

[2] PacifiCare's complaint also states a claim under *Walker Process*. The Federal Circuit has made clear that a *Walker Process* claim is separate and distinct from a claim of sham litigation under *PRE*. *See, e.g., Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059 (Fed. Cir. 1998).

Under their own reasoning, the litigation became moot "in December of 2004" when they introduced the next version. The defendants have no explanation for why they waited an additional five months before dismissing the lawsuits. One logical explanation from the facts as alleged in the complaint is that Abbott and Fournier evaluated the strength of their remaining claims and concluded that they could not prevail. Another explanation is that the defendants waited those additional months to further delay the entry of generic drugs into the marketplace and allow the defendants to convert the market in the interim. Either explanation creates an issue as to whether the lawsuits were objectively baseless, as by defendants' own admission the factual situation did not change between December, 2004 and May, 2005. The defendants' reasons for seeking a voluntary dismissal are quintessential issues of fact, and are inappropriate for adjudication at this juncture.

Moreover, this Court's denial of some of the generic companies' summary judgment motions does not resolve the issue. The most recent authority to address defendants' argument that surviving a summary judgment motion precludes a finding of objective baselessness, rejected it. See *In re Relafen*, 346 F. Supp. 2d at 363-64; *see also Boulware v. State*, 960 F.2d 793, 798 (9th Cir. 1992) (refusing to adopt the per se rule). As Judge Young explained, overcoming a summary judgment motion does not indicate whether there was probable cause to institute a legal proceeding because "evidence suggesting a genuine issue of material fact does not undergo 'extensive testing' on summary judgment, and significantly, undergoes no testing with respect to the credibility of the witnesses." *In re Relafen*, 346 F. Supp. 2d at 363 (citation omitted). In contrast, the Supreme Court's test for objective reasonableness is not based on whether there was

an issue of fact, but whether there is "a reasonable belief that there is a chance that a claim may be valid upon adjudication." *PRE*, 508 U.S. at 62-63 (emphasis added).

Here, the defendants' own voluntary dismissal of the case shows that at the least, a genuine issue of material fact exists as to whether even Abbott and Fournier had a reasonable belief that their claims would be valid upon adjudication. They had the information as to how the claims were likely to develop, and were in a position to evaluate the overall strength of their claims. That they chose to drop the lawsuit is some evidence that a reasonable litigant would find that the claims were objectively baseless.

3. The Tablet Litigation Conduct Has Caused Antitrust Injury to PacifiCare

Abbott and Fournier's argument that PacifiCare has not suffered an antitrust injury from the sham tablet litigation improperly attempts to segregate one piece of the overall scheme to monopolize from the rest of the allegations. Such an approach is not consistent with the caselaw. In *Biovail Corp.*, the court had to consider whether the generic drug company plaintiff had adequately alleged injury. 49 F. Supp. 2d at 760. The court rejected the defendants' contention "that one particular allegation or another did not cause Biovail injury and, therefore, must be dismissed." *Ibid.* Instead, the court recognized that under *Continental Ore*, "the allegations . . . should not be so tightly compartmentalized." *Ibid.* (internal quotation and alteration omitted). The court concluded that it "will not, therefore, consider whether each allegation resulted in antitrust injury." *Ibid.* Instead, it would "examine whether – as a result of all of the violations alleged – Biovail has suffered" antitrust injury. *Ibid.* (emphasis added).

Likewise, in this case, it is inconsistent with *Continental Ore* to separate out each individual allegation and determine whether a particular action caused antitrust injury.

The defendants here do not dispute PacifiCare's antitrust injury as a result of the overall effect of their anticompetitive actions, or indeed of any other individual action. And they cannot do so. PacifiCare has alleged that as a direct and proximate result of Abbott and Fournier's anticompetitive conduct, it suffered an injury in the form of paying higher prices for drugs in the fenofibrate market than it would have paid in a competitive market. *E.g.*, Complaint ¶¶ 5, 7-8. This injury is a type the antitrust laws seek to prevent and "'flows from that which makes defendants' acts unlawful.'" *Pace Electronics, Inc. v. Canon Computer Systems, Inc.*, 213 F.3d 118, 120 (3d Cir. 2000) (quoting *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977)); *see also In re Warfarin Sodium Antitrust Litigation*, 214 F.3d 395, 400-01 (3d Cir.2000). Because Abbott and Fournier do not and cannot dispute that PacifiCare has been injured by the defendants' actions, this court should not engage in a separate analysis to determine whether any individual allegation satisfies antitrust injury.

In any event, Abbott and Fournier incorrectly assert that PacifiCare has not adequately alleged antitrust injury as a result of the sham tablet litigation. A plaintiff establishes antitrust injury where the antitrust violation caused the injury. Here, Abbott and Fournier's litigation conduct prevented the generic drug makers from selling their product as a substitute for TriCor. The defendants maintain, however, that no antitrust injury exists because this Court did not grant summary judgment on the '405 patent. Yet such an assertion presumes that the '405 patent was valid and infringed. These are questions of fact that a jury must decide and are inappropriate for resolution on a 12(b)(6) Motion to Dismiss.

IV. PACIFICARE DOES NOT IMPROPERLY CONFLATE ABBOTT AND FOURNIER

The defendants argue that the inequitable conduct claim against Abbott should be dismissed because the complaint does not allege facts against Abbott with sufficient particularity. The defendants further assert that the claims regarding marketing conduct against Fournier should be dismissed because the allegations against Fournier are merely conclusory. Both arguments are unavailing.

First, PacifiCare has pleaded inequitable conduct against Abbott with sufficient particularity. Abbott ignores paragraphs 80 and 81 of the Complaint, where PacifiCare alleges specifically that Abbott and Fournier were in communication regarding the prosecution of the patents, and that Abbott knew about the inequitable conduct. The complaint then gives an example of such communication. Complaint ¶ 80. These allegations are more than "boilerplate and conclusory" under Rule 9(b). *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1418. Indeed, Abbott concedes that in the Third Circuit, a plaintiff can generally aver "knowledge" under Rule 9(b). *Ibid*; *see also* Motion to Dismiss at 34.

Second, PacifiCare's allegations against Fournier for marketing the drug are sufficient to satisfy the simplified pleading requirement under Rule 8. Unlike the allegations of inequitable conduct, the marketing allegations need only satisfy the much more lenient standard of Rule 8, which requires only a "short and plain statement" showing that the plaintiff is entitled to relief. Fed. R. Civ. P. 8(a)(2). As the Supreme Court has recognized, this rule "must simply give the defendant fair notice of what the plaintiff's claim is and the grounds upon which it rests. This simplified notice pleading

standard relies on liberal discovery rules and summary judgment motions to define disputed facts and issues and to dispose of unmeritorious claims." *Swierkiewicz v. Sorema*, 534 U.S. 506, 512 (2002). *See also Andrx Pharmaceuticals, Inc. v. Elan Corp.*, 421 F.3d 1227, 1234-35 (11th Cir. 2005) (stating that "[w]hile courts had previously applied a heightened pleading requirement in antitrust cases, this view has subsequently been rejected in favor of applying Rule 8(a)'s notice pleading standard" and holding that antitrust claims are "typically inappropriate for a Rule 12 dismissal"); *Twombly v. Bell Atlantic Corp.*, 425 F.3d at 111 ("short of the extremes of 'bare bones' and 'implausibility,' a complaint in an antitrust case need only contain the 'short and plain statement of the claim showing that the pleader is entitled to relief' that Rule 8(a) requires"); *c.f. Pryor v. National Collegiate Athletic Ass'n*, 288 F.3d 548, 564 (3d Cir. 2002) ("[A]s the Supreme Court has recently confirmed, a complaint requires only a 'short and plain statement' to show a right to relief, not a detailed recitation of the proof that will in the end establish such a right."); *Doe v. Smith*, No. 05-1903, 2005 U.S. App. LEXIS 25051, at *2-*3.

V. THIS COURT SHOULD NOT DISMISS THE STATE LAW CLAIMS

All of PacifiCare's state law claims are valid for at least four different reasons. *First*, Abbott and Fournier's argument for dismissal of the state antitrust claims depends on this Court's dismissal of the federal antitrust claims. But as established above, these federal antitrust claims are not subject to dismissal in a 12(b)(6) motion. *Second*, Abbott and Fournier have made no effort to establish why PacifiCare's complaint does not meet all the elements of the antitrust laws of various states. The defendants simply pick a few states and argue that these states generally follow federal antitrust law. Such an argument

does not establish why PacifiCare's complaint is deficient in the claims arising from states where the defendants have cited an opinion, let alone for the states where the defendants have cited no law whatsoever.

Third, for similar reasons, this Court should not dismiss the unfair competition and fraud claims under state law. Abbott and Fournier again have made no effort to show why these claims fail, except for pointing out that a few of the states require consumer deception or fraud as an element of these actions. The defendants have not shown why these state claims should be dismissed. *Fourth*, for those states in which consumer deception or fraud is an element, PacifiCare has more than adequately alleged fraud and deception. As described in detail throughout the Response, some of these allegations include the defendants' deceptively de-listing the TriCor product codes from the NDDF, committing fraud on the Patent Office through their knowing omissions and misstatements, and deceptively listing unenforceable patents in the Orange Book. Consequently, this Court should not dismiss any of the state law claims regardless of how it resolves the federal antitrust issues.

VI. CONCLUSION

PacifiCare's complaint adequately alleges claims under both federal antitrust law and the laws of different states. For the foregoing reasons, this Court should deny Abbott and Fournier's Motion to Dismiss in its entirety.

DATED: December 9, 2005.

Respectfully submitted,

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CERTIFICATE OF SERVICE

This is to certify that on this the 9th day of December, 2005, a true and correct copy of the above and foregoing **(PUBLIC VERSION)** PacifiCare's Response to Defendants' Consolidated Motion to Dismiss was electronically filed with the Clerk of The Court using CM/ECF which will send notification of such filing to all counsel of record.

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